Remarks

Reconsideration of the above application is respectfully requested.

Claims 25 and 28 have been deleted. Claim 29 has been amended.

Claims 17, 19, 21-25, 28, 31 and 32 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lehmann et al. reference, U.S. Patent No. 6,143,883 either alone or in view of the Donzis reference, U.S. Patent No. 5,705,184.

The Examiner interprets the Lehmann et al. reference as describing water-soluble β-(1,3)-glucans suspended in a carrier, with the glucan prepared by enzymatic digesting or cleaving the large water-insoluble molecules of glucan, fractionating the resulting product and lyophilizing the water-soluble fraction. The Examiner further states that the Lehmann et al. reference describes a glucan which is inherently free from the β-(1,6) linkages because it has been enzymatically treated with cellulase. One skilled in the art would know, that cellulases digest, by definition, only β-(1,4) linkages. Consequently, the β glucan described in the Lehmann reference has few or no β-(1,4) linkages, contrary to the Examiner's contention, all β-(1,6) linkages are intact. In distinction, the presently claimed invention describes glucan that is free from repetitive β-(1,6) linkages and consists mainly of β-(1,3) linkages. The present invention dislcoses all linkages, except the branching point linkages, are the β-(1,3) type as described in page 2, lines 18-19 of the specification. Therefore, the glucans described by the Lehmann reference are not similar to and will not lead one skilled in the art to the present invention because the glucans are dissimilar.

The Examiner also concludes that the determination of optimum particle size of the glucan may be done by routine experimentation and obvious to one skilled in the art. The Lehmann reference lyophilizes the glucan for storage

purposes. The lyophilized glucan is reconstituted before use as described in column 3, lines 66-67 of the reference. In distinction, the claimed invention is directed to an improved epithelial resorption of water-soluble β-glucan by formulating and delivering the water-soluble β-glucan as nanoparticles. The formation of nanoparticles is totally divergent from the prior art as it relates to the problem associated with β-glucan resorption. Based on the prior art, one skilled in the art would expect that the most efficient method of formulating water-soluble β-glucan for dermatological use would be to suspend the reconstituted β-glucan in a cream base with an emulsifying agent. Clearly, the claimed invention teaches away from the prior art and is unobvious in view of the prior art references taken singularly or in combination.

The Examiner also states that the Donzis reference teaches that glucans having a particle size of about 200mm or less "stay better suspended in the base carrier...thereby making the glucan particles less likely to fall out of suspension prior to use," which appears in column 2, lines 55-58 etc. of the Donzis reference. This teaching does not suggest that one skilled in the art would know how to make nanoparticles that retain the water-soluble characteristics of a starting material and have improved efficacy as compared to conventional pure water-soluble glucans and microparticular glucans. The presently claimed invention provides water-soluble glucans in nanoparticular form which is resorbed more efficiently by skin and hair and water-soluble glucans completely dissolved are in a microparticular water-insoluble form.

With respect to claims 21 and 32, the references do not provide an efficient concentration of glucan, nor would they be obtained by routine experimentation to provide a sufficient amount to promote the improved efficacy of water-soluble glucan in nanoparticular form to be resorbed by the skin and hair.

Claim 18 has been rejected under 35 USC 103(a) as being unpatentable over the Lehmann reference either alone or in combination with the Engstad et al. reference, WO 95/00032. The Examiner states that it would be obvious to one skilled in the art to modify the compositions in the Lehmann et all reference to employ β-(1,3) glucan isolated from yeast cells from the family *Saccharomyces*. One skilled in the art would not have been motivated to prepare β-(1,3) glucan from yeast cells of the family *Saccharomyces* merely upon a reading of the Engstad and Lehmann et al. references and in addition, the glucan would not be in a nanoparticular form to provide the efficiency of the presently claimed invention. Clearly, this rejection should be withdrawn.

Claims 20 and 29 have been rejected under 35 USC 103(a) as being unpatentable over the Lehmann et al. reference either alone or in combination with the Donzis and further in view of the Ofuchi et al. reference, U.S. Patent No. 4,333,927. The Examiner believes that the Ofuchi et al. reference adds to teachings of this Lehmann and the Donzi references that PVA or polyethylene glycol are conventional gelatinizers for topical compositions. One skilled in the art would not be motivated to create the methods of the claimed invention by merely using PVA as a gel for topical compositions. Whatever topical compositions created by one skilled in the art in following the teachings of the Ofuchi et al reference and the other references, taken singularly or in combination would not produce a nanoparticular water-soluble β-(1,3) glucan which has intact β-(1,3) sidechains and are free from repetitive β-(1,6) linkages to provide for effective resorption by skin and hair of the water-soluble glucans.

With reference to the prior art cited, Applicants respectfully submit that the references, taken singularly or in combination, do not teach or suggest the presently claimed invention. Applicants further submit that the claims meet the requirements of 35 United States Code. Therefore, an early Notice of Allowance of the application is respectfully requested.

Respectfully submitted,

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